

REMARKS

I. Status of the Claims

Claims 1 and 2 are cancelled.

Claims 3, 4 and 5 are amended.

Claims 3-6 are pending.

II. There Are No Art Objections

Applicant thanks the examiner for not rejecting the claims on art (Action, page 11).

III. Claims 3-6 Are Enabled Under 35 U.S.C § 112

The examiner believes that the specification does not enable identifying an adenine at other positions than 307 of the open reading frame within the FUT1 gene. However, claims 3-6 are not directed to identify adenine at other positions. The claims relate to adenine **at position 307** and other homozygous polymorphisms in linkage disequilibrium.

IV. Claims 3-6 Are Not Indefinite Under 35 U.S.C § 112

The examiner, while acknowledging that the specification discloses various molecular methods to determine the specific base pair, believes that claim 3 lacks a step to identify the FUT1 polymorphism. No additional step is needed because any method capable of determining a sequence is suitable. MPEP 2172.01 is based on what applicants' disclosure states is critical, not what the examiner thinks may be critical. There is no need to add a step to define a sequencing method.

V. A Rejection Under 35 U.S.C § 102(f) is Improper Because Applicant Did Invent the Invention in Claims 3-6

The examiner rejected claims 3-6 over U.S. Pat. No. 6,355,859 ('859) (Dr. Bosworth is one of the inventors) under 102 (f). There is a common assignee. A 102(f) rejection is issued if the examiner believes an applicant "derived" an invention from "another" inventive entity. Because the disclosure in the present application and U.S. Pat. No. 6,355,859 are similar, the examiner believes that contributions of the inventive entity are not clear (see page 8 of the Office Action).

a. Inventorship of '859 and the Present Application

Evidence that the invention “an adenine at position 307 of the open reading frame of FUT1 gene is associated with resistance to F18 *E. coli*” was invented by Dr. Bosworth (with Dr. Vögeli) is given on the 1997 priority document, recorded on the declaration of inventorship for the present case. Both '859 and the present application claim priority to the same PCT and provisional applications. Therefore, '859 should not be prior art.

b. Applicant did Invent the Invention as Claims in Claim 3-6 and Therefore Rejection Under 35 U.S.C. § 102(f) is Improper

Both Brad T. Bosworth and Peter Vögeli are joint inventors of the instant invention as evidenced in their Declarations. Because Bosworth and Vögeli are joint inventors on the instant application, they both jointly invented the method for identifying a swine that is resistant to *E. coli* associated intestinal disorders related to the nitrogen base at position 307 as claimed. The '859 patent and the instant patent both claim priority from PCT/US98/10318 which was invented by both Bosworth and Vögeli, which disclosed the importance of the 307 position. Because both of the inventors of the priority document are also inventors of the present invention and the priority invention describes the instant invention, it is clear that the instant invention is invented by the applicants.

Both applications and their priority documents are assigned to Biotechnology Research and Development Corporation and the United States of America as Represented by the Department of Agriculture.

According to MPEP § 706.02(g) the examiner must presume the applicants are the proper inventors unless there is proof that **another** made the invention and that the applicant derived the invention from the true inventor. In the instant application, there is no proof that Bosworth and Vögeli are not the true inventors of the method for identifying swine that is resistant to *E. coli* as determined by the presence of a nitrogen base at position 307. As such, applicant believes that examiner's rejection based on 102(f) is improper and asks that it be removed.

VI. Obviousness-Type Double Patenting Rejections May Require a Terminal Disclaimer

The examiner rejected claims 3-6 over claim 1 in U.S. Pat. No. 6,596,923 (Drs. Bosworth & Vogeli; issued July 22, 2003). Although we disagree, a terminal disclaimer will be filed if claims are allowed.

The examiner rejected claims 3-4 over U.S. Pat. No. 6,355,859B1.

To the contrary, the claims are patentably distinct. The instant application claims a method of **identifying** swine that are resistant to *E. coli* by determining whether the only nitrogen base at position 307 is adenine or a polymorphism in linkage disequilibrium. The '859 patent claims a method of **improving weight gain** in swine that are susceptible to F18 *E. coli* colonization which involves first selecting swine based on the presence or absence of adenine at position 307, then second, feeding swine susceptible to F18 *E-coli* a diet of 40% animal-based proteins which improves weight gain, while feeding other swine a diet with different percentages of animal-based protein which reduces F18 *E. coli* colonization.(Notice of Allowance, page 1 mailed October 10, 2001).

These two inventions are directed towards two different problems. The instant invention does not contemplate the dietary selection of swine susceptible to F18 *E-coli* colonization. Further, the instant invention does not deal with feeding or dietary control of pigs which are susceptible to F18 *E-coli* colonization. It does not teach or suggest any use of feeding pigs various diets to combat F18 *E-coli* disease. Rather, the instant invention provides a method for selecting pigs which are resistant to F18 *E-coli*. In sum, the instant invention is directed to a method of selecting pigs which are resistant to F18 *E-coli* whereas the '859 patent is directed to a method of improving weight gain by genotype. As such, these inventions are patentably distinct and applicant requests that this rejection be removed.

VII. Claims 3-5 Are Not Directed to Just Any *E. coli* Strain

The examiner incorrectly states that the specification is not enabling for other strains of *E. coli* (other than F18). However, claims 3-5 refer to *E. coli* strains that are capable of binding to ECF18R (*E. coli* F18 receptor) and not just any other strain. In addition, the examiner stated that ECF18R was not defined in the specification and incorrectly assumed ECF18R represented an *E. coli* strain (page 9 of the Action) and also implied that ECF18R was a gene (page 8 of the

Action). However, on page 2, line 4 of the specification, ECF18R is defined as E. coli F18 receptor neither a strain or gene.

The examiner is incorrect in stating that only a specific alteration at position 307 is disclosed and that only E. coli strain F18 is disclosed. The disclosure is directed to strains that bind to ECF18R and mentions K strains, and the like. On page 6 of the Action, the examiner admits that "the specification defines several other polymorphism (sic) in the coding regions of the FUT1 and FUT2 genes" but argues there is no evidence other polymorphisms are "associated with any resistance to E. coli....". But claims are limited to genes in linkage disequilibrium with polymorphisms of FUT1 with adenine at position 307 which, as known to those of skill in the art, means these claimed genes are effectively not separable by crossing over from adenine at 307.

VIII. Other Issues

Claim 3 is amended to spell out "*E. coli* F 18 receptor" for "ECF18R." However, the examiner is incorrect that this abbreviation is not spelled out in the specification. It may be found on page 2, line 4 of the specification. The examiner's incorrect term "strain ECF18R" indicates his confusion despite the definition in the specification and the knowledge in the art.

Claim 3 is amended to include that the open reading frame is from SEQ I D NO: 12.

The original Information Disclosure Statement which the examiner never received, was resubmitted on October 29, 2003.

Please charge any fees that might be due in connection with this Information Disclosure Statement to our Deposit Account No. 12-0913 with reference to our attorney docket number (21419-91512)

Respectfully submitted,



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